

Remarks

Upon entry of the present amendment, new claims 50-103 will be pending in the instant application. Claims 1-49 have been canceled without prejudice or disclaimer. Applicants hereby reserve the right to pursue the subject matter encompassed within the canceled claims in a continuing application.

Support for the newly added claims 50-103 is found throughout the application as filed. Specifically, support is found on page 9, lines 7-13 (for ATCC Deposits); page 18, lines 25-26 (for using SEQ ID NO:4 to raise antibodies that bind IL-22); page 18, line 27 to page 19, line 21 (SEQ ID NO:4 is similar to ATCC Deposit); page 76, line 20 (polyclonal, monoclonal, and human antibodies); page 76, line 21 (humanized, chimeric, single chain, and F'ab fragments); page 77, lines 10-14 (human antibodies); page 84, lines 11-28 (humanized antibodies); page 88, line 30 to page 89, line 6 (chimeric antibodies); page 78, line 8-21 (antibodies bind polypeptide variants); page 80, lines 16-22 (use of antibodies); page 81, lines 4-5 (glycosylated); page 81, lines 12-23 (immunizing an animal); page 81, lines 24-26 (hybridoma); page 86, line 24 to page 88, line 20 (polynucleotides encoding antibodies); page 100, lines 14 and page 101, line 7 to page 102, line 7 (Western blot and ELISA assays); and page 97, lines 9-25 (labeled antibodies). Thus, no new matter has been introduced.

The Restriction Requirement

Pursuant to Paper No. 7, mailed March 4, 2002, the Examiner has required an election under 35 U.S.C. §121 of one of Inventions I-XI. The Examiner contends that the inventions are distinct, each from the other.

In response, and pursuant to MPEP§818.02(a), Applicants provisionally elect, *with traverse*, the invention of newly added claims 50-103, drawn to antibodies against the polypeptide of SEQ ID NO:4 and the clone contained in the ATCC Deposit 209665 (IL-22 polypeptides), for further prosecution. Applicants submit that the subject matter of new claims 50-103, while fully supported by the specification as filed as discussed above, does not fall within the scope of the Invention groups defined by the Examiner in the Restriction Requirement. Under MPEP §818.02(a), though, an election may be made by the presentation of original claims to another invention. Applicants contacted the Examiner by telephone on April 1, 2002 to discuss the above provisional election. The Examiner indicated that the presentation of original claims directed to anti-IL-22 antibodies would be considered a proper

provisional election since substantive examination on the merits has not yet been performed. Applicants reserve the right to file one or more divisional applications directed to non-elected inventions should the restriction requirement be made final. In such a case, Applicants retain the right to petition from the additional restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully traverse and request the withdrawal of the requirement for restriction, at least with respect to those claims drawn to the polynucleotides, polypeptides, methods of use, antibodies for IL-21 and for the same claims drawn to IL-22.

Applicants submit that even where two patentably distinct inventions appear in a single application, restriction remains improper *unless* it can be shown that the search and examination of both inventions would entail a “serious burden” (*See* M.P.E.P. § 803). Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the Inventions listed by the Examiner represent distinct and independent inventions, restriction remains improper unless it can be shown that the search and examination of these sequences would entail a “serious burden.” *See* M.P.E.P. § 803. In the present situation no such showing has been made, at least with respect to Inventions I, III, V, VI, VII, VIII, IX and X (drawn to IL-21) and with respect to Inventions II, IV, and XI (drawn to IL-22).

Even assuming, *arguendo*, that Inventions I-XI represent distinct inventions, Applicants disagree with the Examiner’s assertions that to search and examine the subject matter of all the IL-21 or the IL-22 Inventions together would not be a serious burden on the Examiner. Applicants submit that a search of polynucleotide claims of the invention would provide useful information for examining claims directed to both polynucleotides and the polypeptides encoded by these polynucleotides. In certain claims this is especially true because the polynucleotide sequence of these claims is defined in part by the polypeptide that the polynucleotide sequence encodes. Further, Applicants point out that, in many if not most publications, where a published nucleotide sequence is an open reading frame, the authors

also include, as a matter of routine, the deduced amino acid sequence of the encoded polypeptide.

Similarly, a search of the polypeptide claims of the invention would clearly provide useful information for the examination of claims directed to antibodies either produced in response to or having affinity for the subject polypeptides. This is because antibodies are frequently defined by the antigens that they are produced in response to and the epitopes to which they bind. Moreover, in many publications where an antibody is described, the antigen that it was produced in response to is also described.

Further, searches of publications directed to polynucleotides and the use of those polynucleotides would clearly be overlapping. This is so because in many, if not most, publications which describe polynucleotides, these molecules are described by their function, characterization and/or expression profile. Thus, a search of polynucleotide claims would also provide the Examiner with art directed to the manner in which the claimed polynucleotides could be used in diagnostic and therapeutic indications.

Further, searches of publications directed to polypeptides and the use of those polypeptides would clearly be overlapping. This is so because in many, if not most, publications which describe polypeptides, these molecules are described by their function. Thus, a search of polypeptide claims would also provide the Examiner with art directed to the manner in which the claimed polypeptides could be used to treat disease states.

In view of the above, Applicants submit that the searches for polynucleotides, polypeptides, and antibodies; as well as methods of diagnosing, preventing and treating disease states using the nucleic acids and proteins of IL-21 and of IL-22; and methods of identifying a binding partner to a polypeptide of IL-21 or of IL-22; and methods of identifying an activity in a biological assay of IL-21 or of IL-22; and the translational products produced by the methods of identifying an activity in a biological assay wherein said translational products of IL-21 or of IL-22 have said activity, would clearly be overlapping. Accordingly, Applicants request that, in view of M.P.E.P. § 803, the claims of Inventions I, III, V, VI, VII, VIII, IX and X (drawn to IL-21) be examined together and the claims of Inventions II, IV, and XI (drawn to IL-22) be examined together.

Accordingly, Applicants respectfully request that the restriction requirement under 35 U.S.C § 121 be reconsidered and withdrawn.


Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144 should it be made final.

Conclusion

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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